UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	(Subcategory Docket: 06-11337)
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Judge Patti B. Saris
	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S SUR-REPLY IN OPPOSITION TO VEN-A-CARE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: December 18, 2009

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INTRODUCTION

Ven-A-Care does not and cannot contest the law offered by Abbott instructing that summary judgment is not proper on individual elements of a claim. (*See* Abt. Resp. at 12, 17.) For this reason alone, Ven-A-Care's motion should be denied.

Ven-A-Care's motion fails for substantive reasons as well. Whereas Ven-A-Care insists that "Abbott has not identified a genuine issue of material fact" (VAC Reply at 1), the truth is that Abbott contested virtually all facts in Ven-A-Care's Rule 56.1 statement (SOF Resp., Dkt. #525), and also filed its own responsive Rule 56.1 statement setting forth a host of additional facts that preclude summary judgment (SOAF, Dkt. #526). As but a few examples, the following issues (each central to Ven-A-Care's motion) are hotly contested:

- Whether Abbott PPD's WACs for the Ery drugs were "false" when they were in fact (i) the actual prices paid by a significant number of pharmacies for significant sales, (ii) set for legitimate business purposes, (iii) used by Abbott consistent with the U.S. government's definition of WAC, and (iv) reported pursuant to compendia's instructions; and

- Whether – instead of reporting actual WACs, as it did – Abbott should have reported some number that the compendia could then use to compute "an average of the net prices that wholesalers charged providers" (VAC Reply at 6) despite the established facts that (i) Abbott PPD understood that the compendia were surveying wholesalers to set AWPs, (ii) Abbott had no legal obligation to report AWPs or any other number, (iii) the federal Medicaid statute and regulations do not even mention AWP, and (iv) AWP has nowhere been defined as that sort of average.

In the face of these and many other disputed issues of material fact, which must be viewed in the light most favorable to Abbott, the Court should deny Ven-A-Care's motion.[1]

[1] Genuine issues of material facts also preclude summary judgment for Ven-A-Care on the materiality and causation elements and the evidence that Ven-A-Care inaccurately calls the "government knowledge affirmative defenses," none of which Ven-A-Care addresses in its reply brief. For example, Abbott has presented evidence that the state Medicaid programs, with HCFA/CMS's knowledge and blessing, chose to pay the spreads on Ery products for policy reasons, such as the legal mandate to ensure equal access to care for Medicaid patients, the need to compensate for inadequate dispensing fees, and the desire to encourage pharmacies to dispense generic drugs. (Abt. Resp. at 10-11.) Indeed, the average $3 "difference" calculated by Ven-A-Care's expert is less than the amount that the Medicaid dispensing fees were inadequate to cover pharmacies' dispensing costs and in fact was used by the

I. THE COURT SHOULD NOT ENTER "PARTIAL" SUMMARY JUDGMENT ON INDIVIDUAL ELEMENTS OF THE FCA CLAIMS.

As shown in Abbott's response brief, the law counsels against precisely what Ven-A-Care seeks here: summary judgment on elements of a claim. (Abt. Resp. at 12, 17.) Ven-A-Care offers no response to this point. Yet, the rule exists for a reason and, by itself, compels the denial of Ven-A-Care's motion. Indeed, it is difficult to imagine how a piecemeal summary judgment would save the parties or the Court from any burden at trial; the same universe of evidence applies regardless of how many elements are tried. For example Abbott's evidence on falsity applies to the scienter element as well. The Court should follow the well reasoned law, and deny summary judgment on single elements of Ven-A-Care's case.

II. FACTUAL DISPUTES PRECLUDE SUMMARY JUDGMENT ON THE SCIENTER ELEMENT.

Ven-A-Care seeks summary judgment on the scienter element based on the flawed notion that, even though Abbott PPD set its WACs for legitimate business reasons and reported the WAC as the compendia instructed, Abbott PPD nevertheless should have set its WACs to enable the compendia to calculate some sort of average of wholesaler prices. (VAC Reply at 6.) This unwieldy theory raises key factual disputes about Abbott's knowledge and intentions that preclude summary judgment, including the following:

- Abbott PPD consistently had high-margin sales of the Erys at the reported WACs, which Abbott maintained and set for several legitimate, competitive business reasons, without any consideration of spreads or Medicaid "reimbursement." (Abt. Resp. at 4-5.)

- The federal government has defined WAC as Abbott and the rest of the industry generally understood the term: "The manufacturer's list price for the drug or

(continued…)

Medicaid programs to cross-subsidize the inadequate dispensing fees. (Abt. Resp. 10-11.) Because Ven-A-Care does not address these elements and the so-called defense in its reply brief, Abbott will not address them further in this sur-reply.

biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price." (Abt. Resp. at 6 n.5.)

- Abbott PPD reported the WACs to the compendia as the compendia instructed (SOAF ¶ 20) and as Abbott PPD personnel legitimately understood that they were supposed to. (Abt. Resp. at 5-6.)

- No federal Medicaid statute or regulation compels manufacturers to report AWPs, and the government has never defined the term. (SOAF ¶¶ 55-57.)

- Abbott PPD did not set the AWPs for the Ery drugs and refused to verify them for the compendia or anyone else. Indeed, Abbott PPD understood that the compendia set AWPs based on surveys of wholesalers. (Abt. Resp. at 6.)

- Abbott PPD personnel did not market the Ery drugs' spreads (*id*. at 6-7), and did not believe even that they could because they understood (correctly) that no erythromycin manufacturer could position itself to have the highest spread because the Medicaid payments were capped by FULs or MACs. (*Id*. at 7; SOAF ¶ 53.) Furthermore, there is no evidence that Abbott PPD had, or believed that it had, spreads worthy of marketing. (SOAF ¶¶ 18, 19.)

- While Abbott PPD allegedly was "conceal[ing]" its "real" prices from the government, Abbott PPD was reporting its AMPs, which Ven-A-Care's expert concedes was a number that satisfies his definition of AWP. (*Id.* ¶¶ 25-26.)

This Court and many others have recognized that scienter is not ordinarily resolved through summary judgment. (Abt. Resp. at 12-13.) The issues raised in Ven-A-Care's reply brief only prove why this case is no exception.

First, Ven-A-Care gets nowhere by trying to chip at the edges of Abbott's data that show significant sales of the Ery drugs at List Prices and WACs. (*See* SOAF ¶ 6.) Ven-A-Care's quibbles about the exact volume of these sales misses the point that these sales' existence raises a significant factual dispute over whether PPD somehow intended (as Ven-A-Care claims) to report prices it knew to be "false." This is particularly so in the face of evidence that Abbott PPD set the WACs based on legitimate business concerns and reported them as the compendia instructed (and certainly not in contravention of any law).

Second, with no evidence that Abbott PPD actually marketed the spread for Ery products, Ven-A-Care relies on an assertion that Abbott PPD reported the WACs "in a market that was characterized by competition and susceptible to spread inducements." (VAC Reply at 2.) The assertion, however, is wholly unsupported, and in fact is contradicted by the evidence showing that FULs and MACs capped payments and prevented companies from marketing spreads. (SOAF ¶¶ 46-48, 53.) Abbott PPD set the WACs and the discounted contract prices to be competitive in the marketplace. (*Id*. at ¶¶ 4, 17.) There is no evidence that Abbott's pricing was driving the FULs or MACs higher or that the Erys had higher spreads than the other oral erythromycins. Even without these problems, which give rise to disputed issues, this attempt to infer marketing the spread is too thin a reed to support summary judgment.

Third, Ven-A-Care barely addresses the evidence that Abbott PPD did not "set AWPs." (VAC Reply at 2.) Offering no facts about Abbott PPD at all, Ven-A-Care instead relies on arguments made in another brief, in a different case, based entirely on inferences about a different (and now former) Abbott division. (*Id.*) Ven-A-Care ignores that Abbott contested Ven-A-Care's statement of facts on this issue (SOF Resp. ¶¶ 6-12, 14-16) and established that Abbott PPD personnel believed that they appropriately were reporting List Prices and WACs and that the compendia set AWPs based on surveys of wholesalers. (SOAF ¶¶ 27, 29, 32.) With no rejoinder from Ven-A-Care, Abbott's submissions are more than enough to defeat summary judgment.[2]

[2] Ven-A-Care's next argument does not relate directly to Ven-A-Care's proof of scienter, but it is easily dispatched. Ven-A-Care contends that the government reports identified in Abbott's response brief "either do not identify the Abbott Ery drugs or do not show true prices." (VAC Reply at 3.) Neither point is correct. (*See* Abt. Reply in Support of Mot. To Dismiss, Dkt. #542, at 3-7.) Ven-A-Care is also wrong that a single report must "demonstrate approval of, or even acquiescence in," Abbott's price reporting practices. (VAC Reply at 3.) The reports as a whole and the government's decades of inaction certainly are sufficient to establish at least a factual issue about acquiescence. *See, e.g., United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) (recognizing the government's "acquiescence" as "highly relevant" to determining FCA liability); *United States ex. rel. Englund v. Los Angeles County*, 2006 WL 3097941, *12-13 (E.D. Cal. Oct. 31, 2006) (summary judgment granted for defendants because CMS officials had knowledge of the alleged "scheme"; "even if the County caused the State to submit a 'false' claim, the government's knowledge negates the County's intent").

Fourth, Ven-A-Care claims that "Abbott marketed the spread by communicating AWP information in documentation such as product listings, order sheets, sell sheets and stocking sheets." (VAC Reply at 3.) The record shows no such thing. (Abt. Resp. at 6-7 & n.6; SOF Resp. ¶ 33.[3]) Abbott PPD personnel denied ever marketing the spreads on the Ery drugs, and Ven-A-Care has offered nothing to prove otherwise. (SOAF ¶ 18.) Ven-A-Care alludes to third parties disseminating AWP information, but has not responded at all to Abbott's statement that "[t]o the extent that wholesalers or retail buying groups did disseminate any AWP or spread information on the Erys, Abbott PPD was not aware of wholesalers or retail buying groups disseminating any AWP or spread information on the Erys, and Abbott did not authorize such action." (SOAF ¶ 19.)

Fifth, Ven-A-Care's next argument – that Abbott's "reporting of AMP does not negate Abbott's scienter" (VAC Reply at 3) – fares no better. Certainly, these quarterly submissions of prices, which Ven-A-Care's own expert concedes would satisfy Ven-A-Care's definition of AWP (SOAF ¶ 26), establish at least a genuine issue of material fact about Abbott's scienter. Ven-A-Care argues that this Court has addressed this issue in *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127 (D. Mass. 2008), but in that case the defendants argued that the state could "reverse engineer" the AWPs based on the unit rebate amounts. Here, Abbott reported the AMPs directly to the U.S. Government on whose behalf Ven-A-Care is suing. (SOAF ¶ 25.)

Finally, any state's "lower of" payment methodology would not eliminate the genuine issue of material fact with respect to whether states' use of FULs and MACs eliminates any

[3] Ven-A-Care's citation to Thomas Ex. 10 (excerpt of Lehn Dep.) is mysterious because it does not support Ven-A-Care's proposition. Indeed, Mr. Lehn testified that he believed that the "proposed program" was not mailed (Thomas Ex. 10 at 127), that he did not "remember Abbott sending out any letters like those" (*id*. at 126), that AWP was used only as a reference to what a pharmacy would pay without a contract (*id*. at 130), and that the proposed letter had nothing to do with "reimbursement" and would have demonstrated only purchase price savings if the pharmacy participated in a retail buying group (*id*. at 128-29).

incentive to attempt to create or market a spread. Ven-A-Care proffers no evidence that Abbott PPD had, or believed that it had, a spread advantage in the face of these Medicaid payment caps.

III. VEN-A-CARE HAS FAILED TO ESTABLISH A FALSE CLAIM UNDER THE FCA.

Abbott's response brief raised *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25 (D.D.C. 2007), in which the court found no "false or fraudulent claim" based on the defendant hospital's recruiting sicker patients and keeping some patients hospitalized longer in order to increase artificially its base rate under Medicare, which led to inflated Medicare payments. (Abt. Resp. at 25-26.) Ven-A-Care does not challenge the decision's reasoning or the case's similarity to the present one. Instead, Ven-A-Care claims that the First Circuit and the District of Massachusetts have rejected *Hockett*. That is not true. None of the opinions cited by Ven-A-Care directly address whether a false claim existed, and each is easily distinguished.

In *United States v. Rivera*, 55 F.3d 703 (1st Cir. 1995), the defendant hospital officers (who, prior to the civil action, were convicted of criminally conspiring to defraud the government) had pocketed a portion of HUD loan proceeds, obtained through Merrill Lynch, by having the hospital pay inflated prices for furniture and equipment to a company that they owned, but which did not deliver the goods. The defendants' fraud had caused the hospital to default on the loan, which in turn caused Merrill Lynch to receive reimbursement from HUD under federal insurance. *Id.* at 705-07. *Rivera* provides no support for Ven-A-Care's position because the court did not in fact find that the alleged conduct had led to a false or fraudulent claim. In reversing summary judgment for the government based on the statute of limitations, the court merely adopted the parties' agreed position that the "lender's claim in effect completes the perpetrator's violation of the FCA" in order to determine when the claim was made. *Id.* at 705, 707.

United States v. Dynamic Research Corp., No. 03-cv-11965-NG, 2008 U.S. LEXIS 25354 (D. Mass. Mar. 31, 2008), similarly involved employees who earlier had been convicted of defrauding the government. The defendant's employees expressly and purposefully made the Air Force over-pay for computer installation services, memory, and training, for those employees' direct benefit and "in violation of contractual and regulatory conflict-of-interest rules and in breach of their duties to provide honest services to the government." *Id.* at *4. Acknowledging that "[n]ot all fraud conduct gives rise to liability under the FCA" and that the FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment," the court's decision was limited to "where a claim for payment is the result of a fraudulent process – bid rigging, self-dealing, etc. – such that the reliability and trustworthiness of a claim is compromised . . . ." *Id.* at *29-34 (citations omitted); *see also id.* at 36 ("DRC is correct in arguing that the fact that the government may have paid prices above the wholesale price for purchased goods does not make the claims false per se. However, a claim *is* false under the FCA where it is the direct product of secret self-dealing or collusion, as in the bid-rigging cases.") (citations omitted).Ven-A-Care has presented no facts to show that the Medicaid claims' reliability and trustworthiness were compromised by the kind of self-dealing or collusion present in *Dynamic Research*.[4]

Moreover, Ven-A-Care's argument that the Medicaid claims were false because of some underlying fraud, even if accepted as correct, would not merit summary judgment. Ven-A-Care has proffered no evidence to support an allegation that the Medicaid claims at issue were an

[4] Ven-A-Care also cites *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), but there the false claim was the providers' representation that the drugs had been dispensed to a Medicaid patient for an approved use, which was caused by the defendants "off label" marketing campaign, which included fraudulent statements and kickbacks. The defendant did not challenge this point. *See id.* at 51 ("Defendant does not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA.").

intended consequence of any pricing or price reporting by Abbott. Ven-A-Care presents no evidence that Abbott set or reported prices in order to create, maintain, or grow spreads on the Erys. In fact, the alleged spreads shrunk during the fourteen-year claims period. (SOAF ¶ 16.) Ven-a-Care has failed to show any "false or fraudulent claim" as required by both sections of the FCA at issue here. 31 U.S.C. § 3729(a)(1), (a)(2).

IV. FACTUAL DISPUTES ABOUT THE MEANING OF AWP WITHIN MEDICAID PRECLUDE SUMMARY JUDGMENT.

Ven-A-Care's argument that the Court should apply, as a matter of law, Ven-A-Care's plain meaning interpretation of AWP is based entirely on its assertion that "[t]he key here . . . is that the terms AWP and WAC in the Medicaid context are derived from statute and regulations." (VAC Reply at 5; *see also id*. at 7 ("the meaning of the term AWP in the federal statutes and regulations is a matter of law, not fact").) Ven-A-Care never identifies, however, to what statute or regulation it is referring.[5] In fact, the federal Medicaid statute and regulations do not use the term "AWP" or the phrase "average wholesale price." Moreover, no federal statute or regulation requires manufacturers to report AWPs to anyone or has ever defined AWP in any context. (*See* OIG 2005 Report, "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price," at 3 ("The AWP is not defined in law or regulation, and fails to account for the discounts available to various payers."), attached as Berlin Declaration, Ex. 1.)

[5] Ven-A-Care provides only a hint, which proves to be a rabbit hole. Ven-A-Care states that "in the context in which the term AWP appears – as a means to determine a Medicaid program's best estimate of the price generally and currently paid by providers for the drug product – it is clear that the term was used with its plain meaning as an average of the net prices that wholesalers charges (sic) providers." (VAC Reply at 6.) In fact, the "generally and currently paid" provision does not use "AWP" or "average wholesale price." Even if it did, Ven-A-Care's logic would still be flawed. Ven-A-Care does not explain how or why "generally and currently paid" supposedly translates into "an average of the net prices that wholesalers charge providers," a term that Ven-A-Care invents. Ven-A-Care's argument is even further flawed because the referenced provision does not apply to manufacturers, and Ven-A-Care does not explain how its interpretation jibes with the state Medicaid programs' long-time and universal application of discounts (determined through negotiations with pharmacists) to AWPs to arrive at estimated acquisition costs (EACs) and their use of ingredient cost margins to subsidize inadequate dispensing fees. (Abt. Resp. at 10-11.)

Even if the Court could construe the term "AWP" as a legal matter (which it should not), Ven-A-Care does not explain why the Court would not consider the relevant Medicaid officials' expectations about AWP in order to construe the term. The Court certainly may consider extrinsic evidence to construe a statutory term (which, again, AWP is not). *See Train v. Colorado Public Interest Research Group, Inc*, 426 U.S. 1, 10 (1975)("When aid to construction of the meaning of words, as used in the statute, is available, there certainly can be no 'rule of law' which forbids its use, however clear the words may appear on 'superficial examination.'").[6] Indeed, if this Court were to interpret AWP in this case to mean "an average of the net prices that wholesalers charged providers," it would stand alone and in sharp contrast to nearly every witness deposed, from the head of CMS down to state Medicaid officials, and the Court's own expert. (*See e.g.*, SOAF ¶¶ 61, 80, 95.) *See also, In re Pharm. Ind. Avg. Wholesale Price Litig*., 460 F. Supp. 2d 277, 285 (D. Mass 2006).

Moreover, even if the Court could define AWP as a legal matter, doing so would not resolve any element of Ven-A-Care's FCA claims. Abbott PPD reported the actual List Prices and WACs, did not set or report AWPs, understood that the compendia were setting AWPs based on surveys of wholesalers, and refused to verify AWPs. (Abt. Resp. at 5-6.) Ven-A-Care makes no argument that the Court, as a legal matter, can define WAC, as "derived" from a statute, probably because the only statute defining WAC defines it exactly the same as Abbott PPD has during the relevant claims period. (Abt. Resp. at 6 n.5.) For Ven-A-Care to prove falsity with

[6] Ven-A-Care's reliance on the First Circuit's recent opinion in *Blue Cross & Blue Shield v. AstraZenecca Pharms. LP*, 582 F.3d 156 (1st Cir. 2009), is misplaced. The court "reject[ed] plaintiffs' position that . . . any spread between AWP and actual acquisition cost was per se unlawful," and most certainly did not disregard the payors' expectations about the price that manufacturers were reporting. *Id.* at 180 n.19; *see also id.* at 171 ("The district court rooted its ultimate liability finding not in the fact that spreads violated the "plain meaning" of "average wholesale price," but instead in the fact that, inter alia, the spreads exceeded industry expectations."). Indeed, Abbott has presented evidence here that Medicaid officials had no expectation that AWP represented an actual average of net transaction prices and fully expected large spreads, no smaller than the spreads alleged in this case. (SOAF ¶¶ 80, 84.)

respect to AWPs, many factual disputes would have to be resolved in Ven-A-Care's favor, which is exactly opposite of the summary judgment standard. *See Shepley v. Johnson & Johnson*, 582 F.3d 231, 236 (1st Cir. 2009) ("To enter summary judgment . . ., the district court would have first had to view the facts in the light most favorable . . . to the nonmoving party . . ., which is a very different enterprise from the fact-finding engaged in at a bench trial."). The Court would have to find that, even though Abbott PPD set the WACs consistent with the statutory definition of the term and based on legitimate business concerns having nothing to do with Medicaid payments, and even though AWP is nowhere defined in any Medicaid statute or regulation, Abbott PPD should have (a) known that, contrary to Abbott's understanding, the compendia were setting AWPs based only on the WACs that Abbott PPD reported, (b) disregarded its own business concerns and the industry's and the federal government's definition of WAC, and (c) set its WACs to result in the compendia calculating AWPs consistent with some unstated definition of the term.[7]

Nor would plain meaning legal interpretation of AWP avoid the adjudication of the many disputed issues at trial. For example, the jury would still have to consider all the evidence that AWP was not considered "an average of the net prices that wholesalers charged providers" in order to decide scienter, materiality, and causation. *See United States v. Prabhu*, 442 F. Supp. 2d 1008, 1029 (D. Nev. 2006) (defendant does not "'knowingly' submit a 'false' claim when its conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance").

[7] Ven-A-Care refers to a "contention that AWP should be construed to mean essentially any amount it chooses as a List Price, regardless [of] whether that price had any relation to the amount providers were paying in the competitive market place . . . ." (VAC Reply at 7.) That point is a straw man for several reasons: (a) Abbott PPD did not in fact make this argument; (b) even Ven-A-Care does not argue that AWPs were set based on the List Prices (Ven-A-Care argues that WACs were used, but even that point is contested); and (c) the Ery drugs' List Prices were (like the WACs) real prices paid in the market place and set based on competitive factors having nothing to do with Medicaid payments. (SOAF ¶¶ 6, 13-17.)

Ven-A-Care has no legitimate argument to establish falsity, and cannot be awarded with summary judgment.

CONCLUSION

For the reasons stated above and in Abbott's Response, this Court should deny Ven-A-Care's motion for partial summary judgment.

Dated: December 18, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A. Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S SUR-REPLY IN OPPOSITION TO VEN-A-CARE'S MOTION FOR PARTIAL SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 18th day of December, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton